UNITED STATES DISTRICT COURT
FOR THE
WESTERN DISTRICT OF NEW YORK

JOANNE MACSWAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:20-cv-1661
	)	
MERCK & CO., INC.,	)	
	)	
Defendant.	)	

OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO EXCLUDE PLAINTIFF'S CAUSATION EXPERTS DR. SAM MORHAIM AND DR. SHEHZAD MERCHANT AND GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT
(Docs. 26 & 27)

Plaintiff Joanne MacSwan brings this action against Defendant Merck & Co., Inc. alleging that she suffered serious and debilitating injuries as a result of taking FOSAMAX® ("Fosamax"), a medication for the prevention and treatment of osteoporosis. Plaintiff asserts three claims: negligent failure to warn (Count I), strict liability (Count II), and breach of implied warranty (Count IV).[1] On May 23, 2022, Defendant moved to exclude Plaintiff's causation experts Sam R. Morhaim, D.D.S. ("Dr. Morhaim"), and Shehzad S. Merchant, M.D. ("Dr. Merchant") (Doc. 26), and moved for summary judgment. (Doc. 27.) Plaintiff responded on June 20, 2022, and Defendant replied on July 6, 2022. Following a hearing on October 18, 2022, the court took the motions under advisement.

Plaintiff is represented by Alexandria N. Rowen, Esq., and Hugh M. Russ, III, Esq. Defendant is represented by Michael L. Hecht, Esq., Robert G. Scumaci, Esq., and

[1] After Defendant moved for judgment on the pleadings, the court dismissed Plaintiff's design defect claims within Counts I (negligence) and II (strict liability) of Plaintiff's Complaint, as well as her claims for breach of express warranty (Count III), fraudulent misrepresentation (Count V), and fraudulent concealment (Count VI). (Doc. 25.)

Stephen E. Marshall, Esq.

I. Whether Plaintiff's Causation Experts Must Be Excluded.

Plaintiff seeks to introduce the testimony of Dr. Morhaim as an expert witness to support Plaintiff's theory that Fosamax caused her to develop osteonecrosis ("ONJ") of the jaw. ONJ is defined as necrotic bone and may be associated with an array of medical conditions. *See* Doc. 26-2 at 8-10 (explaining that ONJ is characterized by "exposed bone" for a period of eight weeks and can be caused by certain pharmaceuticals as well as by bacterial infections). "BRONJ" is ONJ associated with bisphosphonate use.

Plaintiff seeks to introduce Dr. Merchant's testimony as a treating physician and to offer his opinions based not only on what he learned from his two examinations of Plaintiff but what he gleaned from other physicians' causation opinions.

Under Federal Rule of Evidence 702:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702 requires the court to serve as a gatekeeper for expert testimony, ensuring "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993).

In determining the reliability of expert testimony, the court engages in "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. Under *Daubert* and its progeny, relevant factors include the theory's testability, the extent to which it "has been subjected to peer review and publication[,]" the extent to which a technique is subject to "standards controlling the technique's operation," the "known or potential rate of error," and the

"degree of acceptance" within the "relevant scientific community[.]" *Id.* at 593-94 (internal quotation marks omitted). "[T]he test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Restivo v. Hessemann*, 846 F.3d 547, 576 (2d Cir. 2017), *cert. denied*, 138 S. Ct. 644 (2018) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999)).

"[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). The court has "broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Kumho Tire Co.*, 526 U.S. at 142 (emphasis in original); *see also Restivo*, 846 F.3d at 575 (ruling "the district court has broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case") (internal quotation marks omitted).

Plaintiff, as the proponent of expert witness testimony, must establish its admissibility. *See In re Mirena IUD Prods. Liab. Litig.*, *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 411 (S.D.N.Y. 2016) ("The party offering the [expert] testimony has the burden of establishing its admissibility by a preponderance of the evidence."). For the purposes of a products liability claim, "[g]eneral causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 387 F. Supp. 3d 323, 336 (S.D.N.Y. 2019), *aff'd*, 982 F.3d 113 (2d Cir. 2020) (internal quotation marks omitted).

In determining whether an expert's testimony is admissible, "the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Amorgianos*, 303 F.3d at 267. The court must "make certain that an expert, whether basing [his or her] testimony upon

professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 265-66 (internal quotation marks omitted) (quoting *Kumho Tire Co.*, 526 U.S. at 152).

Courts may exclude expert witness opinions when the moving party demonstrates that those opinions are inadmissible and may grant summary judgment if "the admissible evidence is insufficient to permit a rational juror to find in favor of the plaintiff[.]" *Amorgianos*, 303 F.3d at 267; *see also Brooks v. Outboard Marine Corp.*, 234 F.3d 89, 92 (2d Cir. 2000) (affirming district court's exclusion of expert testimony and grant of summary judgment). "The standard for admissibility is the same at the summary judgment stage as it is at trial." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 411; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997) ("On a motion for summary judgment, disputed issues of fact are resolved against the moving party . . . . But the question of admissibility of expert testimony is not such an issue of fact[.]").

A. Whether Dr. Morhaim's Causation Opinions are Admissible.

Dr. Morhaim is a periodontist with expertise in oral implantology. After dental school, he completed a two-year post-graduate program in periodontics, oral medicine, and implant dentistry. From 1994 to 1996, he served as the Clinical Director of Periodontics and Implant Surgery at Flushing Hospital Medical Center in Queens, New York. Since the mid-1990s, he has maintained a "full time periodontal and implant practice[.]" (Doc. 30-3 at 6.) He is a member of the International Congress of Oral Implantologists, the American Dental Association, the American Academy of Periodontology, and the Northeast Society of Periodontics. Dr. Morhaim has worked as an "expert Dental Legal Consultant" for the past two decades. *Id.* at 13.

He opines:

> Based upon my review of the medical and dental records, deposition transcripts, along with my education and expertise in the field of dentistry since 1990, it is my professional opinion within a reasonable degree of medical/dental certainty, that [Plaintiff's] adverse dental condition was BRONJ, and was directly due to her taking the oral medications Fosamax and Atelvia, a similar medication to treat osteoporosis.

Id. at 5. He also asserts:

> It is my professional opinion after reviewing the records presented to me by the law office of Hodgen Russ, LLP, that many of the dental conditions encountered by [Plaintiff] were directly related to her bisphosphonate use. By conditions I am specifically referring to abscesses, loss of teeth, and most recently in 2018, when a lower left lesion was discovered and diagnosed.

Id. at 11. He concedes that the risk of ONJ from oral bisphosphonates such as Fosamax is "[v]ery low." (Doc. 30-2 at 53) (agreeing that the "risk of [ONJ] in oral bisphosphonate users is 0.001 percent"). He further agrees that Fosamax's benefits exceed the risk of developing ONJ.

Dr. Morhaim never treated or examined Plaintiff. He neither reviewed all of Plaintiff's relevant medical and dental records, nor cites to specific scientific studies or data to support his opinion. Defendant argues that Dr. Morhaim's "limited" experience as a periodontist does not qualify him to opine on "1) how bisphosphonates work; 2) the nature of the relationship, if any, between low-dose bisphosphonates and ONJ; and 3) the diagnosis and treatment of ONJ." (Doc. 33 at 2, 4.) Dr. Morhaim, however, has extensive experience as a periodontist, specializing in dental implants and diseases of the gums and jaw. Although he has not personally researched the relationship between bisphosphonates and ONJ, he has read literature pertaining to bisphosphonates throughout his career. He has also worked with patients taking oral bisphosphonates, requiring him to both understand and explain to them the effects and risks of bisphosphonate drugs.

Dr. Morhaim has diagnosed patients with ONJ, including five patients who developed ONJ while taking bisphosphonate drugs whom he referred to oral surgeons for further treatment.[2] He testified in deposition that he makes an ONJ diagnosis based on

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[2] Dr. Morhaim testified as follows regarding one of those patients:

> Q. And Dr. Morhaim, have you ever been deposed in a case in which it was alleged that a bisphosphonate caused an injury?
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> A. I do recall that there was a case many years ago on behalf of an existing patient of mine when I had a Bayside practice. I don't remember the particulars of the case, but I do remember that it was involving bisphosphonates. And it was early

clinical inspections informed by a "staging process" for ONJ that was delineated by Dr. Ruggiero, who is an expert on ONJ and with whom Dr. Morhaim has consulted. (Doc. 30-2 at 29.) He has never presented papers or speeches related to ONJ or BRONJ. Although he contends he has written peer reviewed papers related to ONJ, he did not identify this research in either his report or his deposition testimony.

Whether a witness is qualified as an expert by his knowledge, skill, experience, training, or education is a "threshold question" that the court must resolve before determining whether his or her opinions are admissible. *Nimely v. City of New York*, 414 F.3d 381, 396 n.11 (2d Cir. 2005). "If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (citing *Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 80 (2d Cir. 1997)).

Although Dr. Morhaim's expertise is not in the specialized area of ONJ, his periodontal experience is closely related. He is therefore qualified to opine generally regarding the diagnosis and treatment of ONJ. *See In re Fosamax Prods. Liab. Litig.*, 688 F. Supp. 2d 259, 268 (S.D.N.Y. 2010) (finding expert qualified because "[h]e has practiced dentistry for over 30 years; he specializes in oralfacial pain and maxillofacial radiology; he keeps up to date with the developments in research regarding BRONJ and has given presentations on the issue; . . . [and] he has treated many patients that he believes developed ONJ from a bisphosphonate"). Any "alleged shortcomings" of Dr. Morhaim's qualifications may be "properly explored on cross-examination" and go "to his testimony's weight and credibility–not its admissibility." *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995).

> on when there was all this talk about the relationship between Fosamax and you know, BRONJ.

(Doc. 30-2 at 7.)

Notwithstanding his qualifications to offer general opinions regarding the diagnosis and treatment of ONJ, in this case, Dr. Morhaim seeks to offer general and specific causation opinions that Fosamax caused Plaintiff's injuries. An expert's testimony must not be conclusory or speculative and must be grounded in reliable evidence. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) ("At trial, proffered expert testimony should be excluded if it is speculative or conjectural[;] . . . the admission of expert testimony based on speculative assumptions is an abuse of discretion[.]") (first alteration in original) (internal quotation marks, alteration, and citation omitted). Defendant contends that Dr. Morhaim's "fail[ure] to identify a single published study or report to support his conclusions" is fatal to his opinion's reliability. (Doc. 26-18 at 14.)

An expert need not base his opinion on scientific studies, *see Amorgianos*, 303 F.3d at 266 ("This is not to suggest that an expert must back his or her opinion with published studies that unequivocally support his or her conclusions."); however, where an expert does not cite to published research, he or she must identify other scientifically valid support. *Compare McCullock*, 61 F.3d at 1043-44 (admitting testimony where expert "could not point to a single piece of medical literature," but relied on his care and treatment of the patient, her medical history, pathological studies, review of material safety data sheets, his training and experience, references to scientific treatises, and use of differential etiology analysis), *with Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (excluding expert who was "unable to point to any studies or, for that matter, anything else" to support the causation opinion he reached using a differential analysis) (internal quotation marks omitted).

Dr. Morhaim testified in deposition that he had read relevant scientific literature during his career, including various articles mailed to his home, however, he "[could not] [c]ite any particular article" and his report references no scientific literature or clinical data. (Doc. 30-2 at 10.) This is not the level of scientific rigor that would be expected in his profession.

To the extent that Dr. Morhaim relies on his dentistry education and experience,

he does not explain how they provide a sufficient basis for his causation opinions. *See* Fed. R. Evid. 702 advisory committee notes to 2000 amendments ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). In other words, he "constructs no bridge from his experience to his conclusions." *Ankuda v. R.N. Fish & Son, Inc.*, 535 F. Supp. 2d 170, 174 (D. Me. 2008).

Dr. Morhaim's professional experience with the relationship between bisphosphonates and ONJ is limited to informal discussions with colleagues[3] and his diagnosis of ONJ in five patients taking oral bisphosphonates, whom he then referred to a specialist for continued treatment. To the extent that he has noticed a correlation between oral bisphosphonates and ONJ in his clinical practice, his observations have been confined to these five patients. His practice in those cases entailed diagnosing ONJ rather than ascertaining its causation. *Cf. In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 170-71 (S.D.N.Y. 2009) (admitting general causation opinions of expert witnesses who did not cite to epidemiological studies but had treated hundreds of patients with BRONJ, authored numerous peer-reviewed articles, served on related expert panels, and cited to other case reports, prevalence studies, and articles). Dr. Morhaim's experience in diagnosing bisphosphonates as the cause of BRONJ is thus extremely limited.

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[3] Dr. Morhaim testified:

> Q: Other than Counsel for [Plaintiff] in this case, has anybody else approached you to provided professional opinions related to the topic of bisphosphonates?
>
> A. Colleagues have approached me over the years with respect to my opinions, based upon experience or literature that I wrote, yes.
>
> Q. And have these been instances where you've given written materials that you prepared?
>
> A. No.
>
> Q. So these were informal conversations?
>
> A. Exactly.

(Doc. 30-2 at 12.)

With regard to the specific causation of Plaintiff's alleged ONJ, Dr. Morhaim reviewed some of Plaintiff's medical records and found that "many of the dental conditions encountered by [Plaintiff] were directly related to her bisphosphonate use[,]" including tooth loss, abscesses, and a lesion on the left side of her jaw. (Doc. 30-3 at 11.) He attributes his conclusion in part to Fosamax's lengthy half-life, extrapolating from his assertion that "[t]he elimination half[-]life of Fosamax is 126 months or approximately 10 years" to conclude that the "effects of Fosamax were present in [Plaintiff's] body" from 2002 to 2021, "three years after the lesion was diagnosed in the lower left jaw." *Id.* at 10. Dr. Morhaim fails to cite a source for this assertion. In deposition, he admitted that his half-life statistic refers to bisphosphonate buried in the bone. He does not adequately address whether the bisphosphonate remained pharmacologically active.[4] Without Dr.

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[4] Dr. Morhaim testified:

> Q. And does the bisphosphonate have a biologic effect while it's buried in the bone? Can it get to the osteoclast?
>
> A. Bisphosphonate has already incorporated itself into the osteoclast and caused the damage. So whether it's while the patient is on the medication or after the patient stops, and it's within that half[-]life, it's doing the same type of damage.
>
> Q. While it's buried in the bone?
>
> A. Correct.
>
> Q. That's your opinion?
>
> A. That is my opinion that it has to be buried in the bone to cause a problem, yes.

(Doc. 30-2 at 76.) Defendant's rebuttal expert report, however, states:

> The half-life of bisphosphonates has been discussed in some of the literature vis-à-vis the issue of ONJ. This discussion is somewhat of a "red herring," as the half-life of bisphosphonates is dependent on the physiologic situation. The half-life of bisphosphonates buried in bone has been estimated at 10 years, but bisphosphonate buried in bone is not pharmacologically active. Bisphosphonates are only pharmacologically active to reduce bone turnover when they are in locations where they can have contact with and be ingested by osteoclasts that are resorbing bone, i.e., on the surface of bone. Indeed, the FDA-approved Fosamax label explicitly states this: "while incorporated in bone matrix, alendronate is not pharmacologically active. Thus, alendronate must be continuously administered to suppress osteoclasts on newly formed resorption surfaces" (Fosamax label). The half-life of bisphosphonates on the surface of bone is estimated to be days to weeks, not years.

Morhaim identifying the studies or data which support his half-life conclusion, the court cannot "determine that [his] opinion is based on sufficient facts or data." *Kellogg v. Wyeth*, 2012 WL 2970621, at *5 (D. Vt. July 20, 2012).

Dr. Morhaim also testified in deposition that a dose of 35 milligrams of Fosamax per week as prescribed to Plaintiff would result in a significantly lower risk of ONJ and that he could not identify any epidemiologic evidence documenting a patient developing ONJ after two years of cessation of bisphosphonate use.[5]

Dr. Morhaim relies on Plaintiff's treatment providers James M. Lesinski, D.D.S., and Lauren Devantier, D.D.S., for his opinion that Plaintiff has BRONJ. Although his report cites clinical observations made by these practitioners, he admitted during his deposition that he had not reviewed Dr. Lesinski's records prior to 2010, which showed that Plaintiff was missing ten teeth in January 2001 before she began taking Fosamax. Moreover, Dr. Lesinski confirmed in deposition that, during his 2001 to 2014 treatment of Plaintiff, there was no radiographic evidence of ONJ and that he did not observe symptoms of it. (Doc. 33-1 at 12.)

Dr. Morhaim's failure to review all of Dr. Lesinski's records and to exclude other

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(Doc. 26-3 at 8) (citations omitted).

[5] Dr. Morhaim testified:

> Q. Now are you aware of any studies, epidemiologic studies or clinical studies indicating that a patient off a bisphosphonate for 10 years is at an increased risk for osteonecrosis of the jaw?
>
> A. No.
>
> Q. Are you aware of any epidemiologic studies [or] other controlled studies indicating that patients off of a bisphosphonate for five years are at an increased risk for osteonecrosis of the jaw?
>
> A. No.
>
> Q. Are you aware of any scientific studies, clinical studies, [or] epidemiologic studies indicating that a patient off of a bisphosphonate for two years is at an increased risk for osteonecrosis of the jaw?
>
> A. No.

(Doc. 26-2 at 26.)

potential causes of Plaintiff's dental conditions undermines the reliability of his opinions. *See Israel v. Spring Indus., Inc.*, 2006 WL 3196956, at *4-5 (E.D.N.Y. Nov. 3, 2006) (observing "gaps" in an expert's analysis caused by his failure to review the plaintiff's complete medical records or to conduct a differential analysis to exclude "other alternative possible causes") (internal quotation marks omitted). Although Dr. Morhaim testified that a partial denture could cause gum tissue to separate from the jawbone and that "[s]moking plays a contributing role in any dental infection[,]" (Doc. 30-2 at 96), beyond noting that a denture could be a "catalyst" (Doc. 30-3 at 8), his report fails to rule out these alternative causes of Plaintiff's alleged ONJ.

Dr. Morhaim's discussion of potential non-Fosamax causes of Plaintiff's dental conditions dismisses those causes without an adequate explanation, which is problematic in light of his acknowledgment that he is unaware of any case reports or "epidemiologic evidence indicating that 35 milligrams of Fosamax puts someone at an increased risk for ONJ." (Doc. 30-2 at 69.) Dr. Morhaim's failure to "rule in" 35 milligrams of Fosamax as the cause of Plaintiff's ONJ is exacerbated by his failure to "rule out other potential causes for the injury at issue" and to "do so using scientifically valid methodology." *Ruggiero*, 424 F.3d at 254 (internal quotation marks omitted).

"[E]ven though an expert need not rule out every potential cause in order to satisfy *Daubert*, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." *Davids v. Novartis Pharms. Corp.*, 857 F. Supp. 2d 267, 278 (E.D.N.Y. 2012) (internal quotation marks omitted). In this case, Dr. Morhaim not only fails to address alternative causes, he sees no reason to do so. During his deposition, he testified: "If the patient is on that [bisphosphonate] medication, and there's clinical evidence of BRONJ, then it's related and caused by that medication being in the patient's system." (Doc. 30-2 at 74.) He testified that BRONJ is also the diagnosis even if a patient has been "off of a bisphosphonate and it's still within the half[-]life of that medication and the patient develops clinical criteria associated with BRONJ[.]" *Id.* at 73. According to Dr.

Morhaim, diagnosis of BRONJ under these circumstances is "by definition[.]" *Id.*[6]

Despite his acknowledgment during his deposition that exposed bone for eight weeks is a necessary criterion for a BRONJ diagnosis, Dr. Morhaim did not use this definition in diagnosing Plaintiff because his report notes a single instance of Plaintiff being diagnosed with a lesion with exposed bone by Dr. DeVantier in May 2018.[7] He

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[6] Dr. Morhaim testified:

> Q. Right, well BRONJ, it simply refers to when ONJ refers to a relationship to a bisphosphonate, correct?
>
> A. Yes, but if the patient is on medication, it's related by definition. That's how you differentiate between osteomyelitis and the medication causing the osteonecrosis, otherwise the criteria would change.
>
> Q. Right, the R stands for related, correct, the R in BRONJ?
>
> A. Oh, yes. Yes. Yes. Yes.
>
> Q. The R in BRONJ stands for related, correct?
>
> A. Yes.
>
> Q. It doesn't mean causation, does it?
>
> A. Well, how do you differentiate between cause and related? If the patient weren't on that medication, then it would be osteomyelitis. The fact that they were on it, that means that it had to have caused it or caused it based on the relationship between the medication and what the patient was experiencing.
>
> Q. That's not what Dr. Ruggiero, says, is it?
>
> A. Well, this is semantics, I think Dr. Ruggiero -- and I know Dr. Ruggiero would agree that if the patient weren't on that medication we wouldn't be calling it BRONJ, but if the patient is on that medication, it is definitely BRONJ. Relation has to do with whether the patient was on the medication or not.

(Doc. 30-2 at 73-74.)

[7] Dr. Morhaim testified:

> Q. But in order to be in this first stage, . . . you still have to have the presence of exposed bone recognized by a physician for eight weeks?
>
> A. Recognized by a dentist.
>
> Q. For eight weeks?
>
> A. Yes.
>
> Q. Okay. And you would agree with me that if you do not have exposed bone for eight weeks, you cannot have this first stage of BRONJ?

does not address the testimony of Dr. DeVantier and Dr. Merchant stating that they did not observe exposed bone during an eight-week period. "Unfounded extrapolations not supported by, or sufficiently related to, scientific data or expertise should be rejected; opinion that 'is connected to existing data only by the *ipse dixit* of the expert' need not be admitted." *In re Zyprexa*, 489 F. Supp. 2d at 284 (quoting *Joiner*, 522 U.S. at 146).

Dr. Morhaim's report also notes that Fosamax's "effects were synergistic with the addition of Atelvia in 2011[,]" (Doc. 30-3 at 11), and states, "[n]ecrotic bone was most likely caused by osteoporotic medication prescribed (Alteria)." *Id.* at 8. Dr. Morhaim acknowledged in his deposition, however, that Atelvia is an oral bisphosphonate and that he had "[n]o reason to believe, based upon scientific evidence, that the risk of osteonecrosis of the jaw with Atelvia, is any different than it is with Fosamax[,]" and he did not compare the quantities of Atelvia and Fosamax that Plaintiff was prescribed. (Doc. 30-2 at 82.)[8]

For the reasons stated above, because Dr. Morhaim's general and specific causation opinions lack the reliability required by Rule 702 and *Daubert*, they are inadmissible. *See Joiner*, 522 U.S. at 146 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence [when] . . . there is simply too great an analytical gap between the data and the opinion proffered."). Even if Dr. Morhaim's opinions were admissible, expert testimony may still be excluded under Fed. R. Evid. 403 if its "probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, [or] misleading the jury[.]" Fed. R. Evid. 403. These dangers are particularly pronounced in the context of expert testimony, given the unique weight that a jury may place on such testimony. *See Daubert*, 509 U.S. at 595 ("Expert evidence can be both powerful and quite misleading because of

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A. That's the criteria that we follow, yes.

Id. at 32.

[8] Plaintiff's medical records indicate that she took Atelvia for approximately eight years, Boniva in 2011, a generic alendronate in 2008, and Fosamax from approximately 2002 to 2006. The parties dispute whether Plaintiff took Fosamax on a consistent basis during the latter time period.

the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.") (internal quotation marks omitted); *see also Nimely*, 414 F.3d at 397 (noting the "unique weight such [expert testimony] may have in a jury's deliberations").

Allowing Dr. Morhaim to offer causation opinions based on inadequate support would be "highly prejudicial and have the potential to confuse and mislead the jury as to the role of an expert witness, the limits of his or her knowledge, and interpose the risk that a jury would find such opinions by a[n] . . . expert such as [Dr. Morhaim] conclusive." *Doe v. Hartford Sch. Dist.*, 2018 WL 1064572, at *6 (D. Vt. Feb. 26, 2018).

Because Dr. Morhaim's causation opinions are inadmissible under Rule 702, *Daubert*, and Rule 403, the court GRANTS IN PART and DENIES IN PART Defendant's motion to exclude his testimony at trial. Dr. Morhaim may testify regarding the diagnosis and treatment of ONJ. He may not, however, proffer a general or specific causation opinion regarding Plaintiff's alleged ONJ.

B. Whether Dr. Merchant's Treating Physician Opinions are Admissible.

Dr. Merchant attended medical school at Aga Khan University in Pakistan before interning at Rochester General Hospital and completing his residency at the University of Texas Saint Paul's Medical Center. He completed an infectious disease fellowship at the University of Rochester Medical Center and is board certified in internal medicine and infectious diseases. In addition to treating patients, Dr. Merchant is the director of antimicrobial stewardship at the University of Rochester.

In his deposition, Dr. Merchant testified that, as the hospital's director of antimicrobial stewardship, he "review[s] cases with pharmacy almost on a daily basis in making sure that patients are on appropriate antimicrobial agents to help reduce rate of resistance, clostridium difficile, and other complications that can come about with prolonged and inappropriate use of antibiotic therapy." (Doc. 30-4 at 74.) Dr. Merchant has not conducted research or lectured regarding bisphosphonate drugs. He is not trained as a dentist or oral surgeon.

On July 3, 2018 and July 31, 2018, Dr. Merchant evaluated Plaintiff at Buffalo General Medical Center. Both before and after his evaluations, he did not review Plaintiff's medical or dental records and he was unaware of when, how long, and what dosage Plaintiff took of Fosamax. Dr. Merchant never spoke to Plaintiff's dentists, Dr. Lesinski or Dr. DeVantier, about their treatment of Plaintiff, nor did he review their records. Although he noted during his examination of Plaintiff that she was missing several teeth, he did not know when, how, or why she lost them.

After his two examinations of Plaintiff, Dr. Merchant "concurred with" another physician's "diagnosis of osteomyelitis on [the] basis of history, prior imaging, and elevated inflammatory markers[.]" *Id.* at 45-46. He noted Plaintiff's CT scan report and dental evaluation stated that "prior bisphosphonate use" was the cause of Plaintiff's ONJ. *Id.* at 47. He based his knowledge of Plaintiff's bisphosphonate use on "the information in the Buffalo General and ECMC medical records as well as what [Plaintiff] told [him.]" *Id.* at 50. Dr. Merchant acknowledged that a BRONJ diagnosis was made before he examined Plaintiff:

> Q. Do you feel, Doctor, that you did an exhaustive review of the literature related to the topic of bisphosphonates and osteonecrosis of the jaw?
>
> A. At the time when I had seen the patient, I had reviewed some literature with regards to this. I cannot recall all the papers that I reviewed at that time. This was three years ago. *This was a diagnosis made before we saw the patient.* We saw the patient primarily for a complication of this diagnosis, not this diagnosis itself.

(Doc. 26-15 at 8-9) (emphasis supplied).

Plaintiff did not disclose Dr. Merchant as an expert witness under Fed. R. Civ. P. 26(a)(2)(B) and conceded during oral argument that Dr. Merchant may not offer an opinion on causation. She instead seeks to introduce Dr. Merchant's testimony for the purpose of establishing that he personally examined Plaintiff, diagnosed her with osteomyelitis, and concluded that Plaintiff's CT scans showed ONJ.

"It is well settled that a treating physician is not subject to the disclosure obligations set forth in Fed. R. Civ. P. 26(a)(2)(B)[,]" *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 472 (E.D.N.Y. 2011) (internal quotation marks omitted), because he

or she is not "retained or specially employed to provide expert testimony in the case[.]" Fed. R. Civ. P. 26(a)(2)(B). "[W]hen [a] doctor's opinion testimony [as a treating physician] extends beyond the facts disclosed during the care and treatment of the patient . . . , he or she is subject to the provisions of Rule 26(a)(2)(B)." *Pokigo v. Target Corp.*, 2014 WL 6885905, at *4 (W.D.N.Y. Dec. 8, 2014).

"Generally, a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness." *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009). The failure to provide a written report under Rule 26 means the treating physician is barred from "testifying concerning opinions not gleaned from his own diagnoses and treatment of the [patient]." *Barack v. Am. Honda Motor Co.*, 293 F.R.D. 106, 109 (D. Conn. 2013) (internal quotation marks omitted); *see also In re Aredia & Zometa Prods. Liab. Litig.*, 2009 WL 2496859, at *2 (M.D. Tenn. Aug. 13, 2009) ("The treating physician for whom no expert report is supplied is not permitted to go beyond the information acquired or the opinion reached as a result of the treating relationship to opine as to the causation of any injury[.]").

As a physician who evaluated Plaintiff on two occasions for the purpose of providing medical care, Dr. Merchant "may testify to events and opinions arising directly through [his] treatment of the patient." *Ellerton v. Ellerton*, 2010 WL 11635765, at *5 (D. Vt. Sept. 3, 2010) (internal quotation marks omitted). Because he may "describe what [he] has seen, describe and explain [his] diagnosis and the treatment [he] prescribed, and offer [his] opinions and expert inferences therefrom[,]" *id.* (internal quotation marks omitted), he may testify regarding his concurrence with his colleague's diagnosis that Plaintiff had osteomyelitis. As he reviewed Plaintiff's CT scans, laboratory data, and dental evaluation as part of his treatment, he may further testify regarding his observations of those sources, including that Plaintiff's CT scans showed "fragmentation and lucency of the bone, of the mandible itself, of the parasymphyseal mandible [that were] suggestive of osteonecrosis." (Doc. 30-4 at 47.)

However, "when a physician consults medical records or reviews opinions of other

doctors, compliance with Rule 26(a)(2)(B) is required[,]" *Pokigo*, 2014 WL 6885905, at *4, because a treating physician's causation "opinion is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." *Deutsch*, 768 F. Supp. 2d at 472 (internal quotation marks omitted). Permitting Dr. Merchant to opine regarding another provider's causation opinion would impermissibly allow him to serve as a conduit for another witness's testimony.[9] Dr. Merchant therefore may not opine regarding the causation opinions of other treatment providers, including any opinion in Plaintiff's medical records that she had BRONJ. *See In re World Trade Ctr. Lower Manhattan Disaster Site Litig.*, 2014 WL 5757713, at *5 (S.D.N.Y. Nov. 5, 2014) (requiring plaintiffs to "provide expert reports pursuant to FRCP 26(a)(2)(B)" before eliciting treating physician testimony "based upon facts, evidence, or expertise outside the scope of the individual [p]laintiffs' course of treatment[,]" including "opinion testimony regarding causation that was not formed solely during consultation with, and treatment of, a particular Plaintiff").

For the reasons stated above, the court therefore GRANTS IN PART and DENIES IN PART Defendant's motion to exclude the testimony of Dr. Merchant. Dr. Merchant may testify as a treating physician regarding his examination and treatment of Plaintiff. He may not serve as a conduit for other treatment providers' opinions regarding the cause of Plaintiff's alleged ONJ.

II. Defendant's Motion for Summary Judgment.

A. Undisputed Facts.

In 1995, the Food and Drug Administration ("FDA") approved Fosamax, a

[9] *See Hutchinson v. Groskin*, 927 F.2d 722, 725 (2d Cir. 1991) (finding that counsel improperly used an expert "as a conduit for hearsay testimony"); *Malletier v. Dooney & Bouke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007) ("[T]he expert witness must in the end be giving his *own* opinion. He cannot simply be a conduit for the opinion of an unproduced expert.") (emphasis in original); *Rotman v. Progressive Ins. Co.*, 955 F. Supp. 2d 272, 283 (D. Vt. 2013) ("To the extent [an expert] merely repeats or recasts the testimony of [another witness] in order to arrive at a theory of causation, he is not testifying as an expert witness based upon specialized knowledge, but rather is acting as a conduit for another witness's testimony in the guise of an expert's opinion.").

bisphosphonate drug Defendant manufactures and sells, for the treatment of osteoporosis and Paget's Disease. The FDA later approved the use of Fosamax in the prevention of osteoporosis as well.

In November 2001, Plaintiff received a prescription for Fosamax after she was diagnosed with osteopenia with a low bone mass that increased the risk of bone fractures and the development of osteoporosis. According to Dr. Lesinski, her dentist from 2001 to 2014, she was missing ten teeth at that time. *See* Doc. 32-1 at 6 ("Q. [Y]ou told us before, of the teeth that were missing from [Plaintiff's] mouth as of January 2001, teeth 1 all the way up through 30. Do you recall that? A. Yes. . . . Just to be exact, I said [teeth] 1, 2, 15, 16, 19, 20, 28, 30, 31, and 32.").

Between August 2002 and September 2010, Certified Registered Nurse Practitioner Helen Murphy ("CRNP Murphy") was Plaintiff's "Fosamax prescriber[.]" (Doc. 31-18 at 4.) Plaintiff's medical records from August 2003 indicate that she was a daily cigarette smoker for thirty years but stopped smoking in 2003 after having a biopsy for precancerous changes in her mouth.

In 2005, Defendant updated its FDA-approved Prescribing Information for Fosamax to warn of the risk of ONJ in patients taking bisphosphonates:

> *Dental*
>
> Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, and co-morbid disorder (e.g., pre-existing dental disease, anemia, coagulopathy, infection).
>
> Patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy should receive care by an oral surgeon. Dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk for ONJ. Clinical judgment of the treating physician should guide the management plan of each patient

based on individual benefit/risk assessment.

(Doc. 27-2 at 14) (emphasis in original). Defendant also updated the language of the "Adverse Reaction" section of the Fosamax Prescribing Information as follows:

> *Post-Marketing Experience*
>
> The following adverse reactions have been reported in post-marketing use: . . . Localized osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported rarely (see PRECAUTIONS, *Dental*).

Id. at 20 (emphasis in original).[10]

The majority of ONJ cases occur in patients taking high doses of intravenous bisphosphonates. Although it is possible to develop ONJ while taking an oral bisphosphonate, even Plaintiff's expert witness, Dr. Morhaim, concedes the risk is "very low" at 0.001 percent. (Doc. 30-2 at 53.)

In 2005, Defendant revised its Fosamax Patient Information Sheet to state that "patients have had jaw problems associated with delayed healing and infection, often following tooth extraction." (Doc. 27-3 at 3.) By 2007, Dr. Lesinski was aware of the alleged association between oral bisphosphonate use and ONJ. (Doc. 33-1 at 6.)

Dr. Lesinski testified that between 2001 and 2014 Plaintiff "did not present with any clinical presentation consistent with necrosis in her jaw" or have any radiographic signs of ONJ. *Id.* at 12; *see also id.* at 9 ("Q. [A]m I correct, at no time during 2010 did you see any exposed bone? Is that correct? A. Correct. Q. And at any time during 2010, did you see any evidence -- clinical evidence of any necrotic bone? A. No.").[11] He believed Plaintiff's "major problem was [tooth] decay" caused by mouth bacteria which, in turn, resulted from smoking and xerostomia.[12] (Doc. 26-10 at 8.) He testified:

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[10] Defendant's patent rights to Fosamax expired in February 2008.

[11] Although Plaintiff asserts that "Dr. Lesinski first made the diagnosis that [she] was suffering from BRONJ" (Doc. 30 at 7), this statement is unsupported by the record and contradicts the admission in her response to Defendant's Statement of Undisputed Material Facts that she was diagnosed with ONJ in 2018. Dr. Lesinski stopped treating Plaintiff in 2014. *See* Doc. 26-10 at 19 ("Q. So you stopped seeing [Plaintiff] as a patient, I believe you said, in July of 2014; is that correct? A. That's correct.").

[12] Xerostomia is dryness of the mouth.

> Q. And the decay in her teeth that you were treating her for, we can agree that was not related to her use of bone density drugs; correct?
>
> . . .
>
> [A.] It was not.
>
> . . .
>
> Q. The decay in her teeth was related to the bacteria that was present in her mouth?
>
> A. Yes.
>
> Q. And the bacteria was due, in part, to her smoking and xerostomia?
>
> A. Yes.

(Doc. 33-1 at 12-13.)

In 2011, Dr. Olivia Smith-Blackwell began prescribing Plaintiff Atelvia, a different brand-name bisphosphonate drug that Defendant does not manufacture. In doing so, Dr. Smith-Blackwell discussed with Plaintiff the risk of ONJ associated with bisphosphonate drugs. Dr. Smith-Blackwell nonetheless prescribed and Plaintiff continued to take Atelvia from February 2011 through 2015.

Dr. DeVantier, Plaintiff's dentist from 2014 to 2021, testified that she did not identify any clinical signs of ONJ from 2014 until May 2018. *See* Doc. 27-11 at 9 ("Q. Prior to May 1, 2018, had there been any occasion when [Plaintiff] had presented to you with any clinical presentation that could be considered consistent with osteonecrosis of the jaw? A. No.").

On May 1, 2018, Plaintiff presented with pain on the left side of her jaw. Dr. DeVantier examined Plaintiff and noted a "lump on the lingual side of her mandible at the area of tooth 20[.]" (Doc. 26-12 at 17.) She observed an "inflamed lesion approximately [eight] millimeters in diameter" with a "central white lesion" that was consistent with a sinus tract and had the consistency of bone. *Id.* at 18, 20 (defining a sinus tract as "usually a connection from somewhere within the bone to the external surface indicating an infection"). Dr. DeVantier's observation was consistent with a torus, a bony growth on the inside of the lower jaw, rubbing against Plaintiff's denture and causing the tissue in between the denture and the torus to break down and become

inflamed and infected.

On May 10, 2018, Dr. DeVantier examined Plaintiff again. At that time, Plaintiff reported having no pain and Dr. DeVantier did not see any exposed bone. Dr. DeVantier again observed a torus on Plaintiff's jaw that appeared to be rubbed and irritated by her denture. She referred Plaintiff to Dr. Vukas, an oral surgeon. Dr. DeVantier's notes state that Plaintiff reported Dr. Vukas did not know what was causing Plaintiff's pain and ordered a CT scan.

Seven weeks later, on June 29, 2018, Plaintiff presented at Erie County Medical Center for a CT scan and reported a "protruding area" on her "inside lower left gums." (Doc. 31-8 at 2) (capitalization omitted). Plaintiff's initial Emergency Room ("ER") assessment noted that she had been sent to the ER by her oral surgeon for possible ONJ. The radiologist who administered the CT scan noted that "the parasymphyseal mandible, left more so than right suggest osteonecrosis although chronic osteomyelitis can have a similar CT appearance. Correlation for bisphosphonate therapy is recommended." (Doc. 26-13 at 7.) The CT scan also revealed a brain aneurysm. Plaintiff's Erie County Medical Center records note: "Oral surgery evaluated the patient and recommended treating this as osteonecrosis of the jaw. They recommended getting an infectious disease consult." (Doc. 31-8 at 10.)

Plaintiff was transferred to Buffalo General Hospital, where she was examined by infectious disease consultant Dr. Nikolaos Almyroudis on July 1, 2018. On July 3, 2018, Dr. Almyroudis's partner, Dr. Merchant, saw Plaintiff and noted that Plaintiff was taking antibiotics to treat the infection in her jaw and had lost many teeth, although her remaining teeth were "intact" and her gum tissue was "viable." (Doc. 26-15 at 22, 25.) He did not observe swelling in Plaintiff's gums, any areas of gums that were necrotic, or any exposed bone. Plaintiff's July 5, 2018 discharge records from Buffalo General Hospital state that Plaintiff reported being unable to eat due to jaw pain and that her CT scan demonstrated ONJ on the left side of her jaw.

On July 13, 2018, Plaintiff saw Dr. Justin Au, an oral and maxillofacial surgeon and advised him that she had an "almost [twenty]-year history [of] use of [F]osamax and

[Atelvia] for osteopenia." (Doc. 26-16 at 8.) She further reported "significant improvement" since seeing Dr. Merchant and beginning an intravenous antibiotic. *Id.* at 10 (internal quotation marks omitted). Dr. Au did not observe any exposed bone.

On July 26, 2018, Plaintiff had a follow-up appointment with Dr. Merchant, who noted that Plaintiff was feeling better and that her gum inflammation and jaw pain, tenderness, and inflammatory markers had improved. He did not observe any exposed bone. The next day, on July 27, 2018, Plaintiff again saw Dr. Au, who noted that her infection had improved in response to antibiotics and that she reported "doing well and having no pain[.]" *Id.* at 14. Dr. Au did not observe any exposed bone but ordered a CT scan that revealed "features consistent with infection or osteonecrosis." *Id.* at 17 (internal quotation marks omitted). Plaintiff saw Dr. Au on August 15, 2018 and September 28, 2018. During those visits, Dr. Au noted Plaintiff's condition was stable and that she had no exposed bone.

When Plaintiff saw Dr. DeVantier on December 4, 2018, she had no clinical symptoms of ONJ. Plaintiff saw Dr. DeVantier several times between 2018 and 2021 during which Dr. DeVantier did not observe any necrotic or exposed bone.

B. Disputed Facts.

The parties disagree regarding the extent of Plaintiff's compliance with her Fosamax prescription regimen and the amount of Fosamax that Plaintiff consumed. Defendant contends that Plaintiff was "non-compliant[,]" taking Fosamax on a "limited, intermittent basis with multiple extensive periods" during which she did not take the drug at all. (Doc. 27-1 at 4) (internal quotation marks omitted). CRNP Murphy testified in deposition that her clinical notes from examining Plaintiff in September 2004 state: "I did give her a prescription for Fosamax last year, and she has been really intermittent in the compliance of Fosamax[.]" (Doc. 27-7 at 11) (internal quotation marks omitted). Her clinical notes from Plaintiff's annual exam in 2007 state that Plaintiff was "non-complian[t] to Fosamax[.]" (Doc. 31-2 at 4.) Defendant further points out that between January 2001 and December 2008, Plaintiff was prescribed and filled prescriptions for enough Fosamax to last for twenty-eight months or about thirty percent of that seven-year

period.

After Defendant's patent rights to Fosamax expired, pharmacists substituted generic alendronate tablets for Fosamax when filling Plaintiff's prescription in December 2008. CRNP Murphy testified that she could not "recall any occasion when [she] insisted that a patient take Fosamax when generic alendronate was otherwise available" and could not "come up with a reason why [she] would do that[.]" (Doc. 27-7 at 20-21.) As a result, Defendant asserts that "[t]here is no documentary evidence that Plaintiff received Fosamax at any point after 2006[,]" twelve years before her ONJ diagnosis. (Doc. 27-1 at 4.)

Plaintiff responds that even if her pharmacy records show limited prescription refills, she took Fosamax regularly and "obtained it from other sources." (Doc. 31-18 at 5.) She cites her medical records and deposition testimony from her daughter, Christy Feightner, to demonstrate that she continued to be prescribed Fosamax later than 2006 and that she took Fosamax for more than ten years. Ms. Feightner testified that, although she did not have personal knowledge of Plaintiff taking Fosamax during 2006 or 2007, "[i]f it was prescribed, she would be taking it[.]" (Doc. 31-5 at 16.) CRNP Murphy's clinical notes from Plaintiff's September 25, 2009 annual exam state that Plaintiff was being prescribed Fosamax at that time. As of Dr. Smith-Blackwell's February 9, 2011 examination of Plaintiff, however, Dr. Smith-Blackwell wrote that she directed Plaintiff to "D/C [discontinue] Boniva" and "start Atelvia 35mg [per] wk." (Doc. 31-3 at 2.) Her clinical notes do not reference Fosamax. Plaintiff denies pharmacists began filling her Fosamax prescriptions with generic alendronate tablets in 2008, noting that CRNP Murphy's testimony does not affirmatively support this claim.

C. Standard of Review.

The moving party always "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks

omitted). "Once the moving party demonstrates that there are no genuine issues of material fact, the nonmoving party must come forth with evidence sufficient to allow a reasonable jury to find in its favor." *Spinelli v. City of New York*, 579 F.3d 160, 166 (2d Cir. 2009) (internal quotation marks and brackets omitted). "Thus, a nonmoving party can defeat a summary judgment motion only by coming forward with evidence that would be sufficient, if all reasonable inferences were drawn in its favor, to establish the existence of an element at trial." *Id.* at 166-67 (internal quotation marks and brackets omitted).

The court must grant summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is 'material' . . . if it 'might affect the outcome of the suit under the governing law.'" *Rodriguez v. Vill. Green Realty, Inc.*, 788 F.3d 31, 39 (2d Cir. 2015) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "A dispute of fact is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Id.* at 39-40 (quoting *Anderson*, 477 U.S. at 248). The court "construe[s] the evidence in the light most favorable to the non-moving party" and "resolve[s] all ambiguities and draw[s] all permissible factual inferences in favor of the party against whom summary judgment is sought." *Lenzi v. Systemax, Inc.*, 944 F.3d 97, 107 (2d Cir. 2019) (internal quotation marks omitted). There is no genuine dispute where "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party[.]" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

"The function of the district court in considering the motion for summary judgment is not to resolve disputed questions of fact but only to determine whether, as to any material issue, a genuine factual dispute exists." *Kaytor v. Elec. Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010). "A non-moving party cannot avoid summary judgment simply by asserting a 'metaphysical doubt as to the material facts.'" *Woodman v. WWOR-TV, Inc.*, 411 F.3d 69, 75 (2d Cir. 2005) (quoting *Matsushita*, 475 U.S. at 586). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be

granted." *Anderson*, 477 U.S. at 249-50 (citations omitted). However, if the evidence "presents a sufficient disagreement to require submission to a jury[,]" the court should deny summary judgment. *Id.* at 251-52. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Kaytor*, 609 F.3d 537 at 545 (internal quotation marks omitted) (emphasis omitted).

The summary judgment "standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; . . . [o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 247-48 (emphasis in original).

Although certain facts are disputed in this case regarding Plaintiff's use of Fosamax, they are not material to any essential element of Plaintiff's claims, including the adequacy of the Fosamax warning label, Defendant's alleged failure to warn Plaintiff's Fosamax prescriber, or whether Defendant breached the implied warranty of merchantability in its manufacture and sale of Fosamax.

D. Whether Defendant Is Entitled to Summary Judgment on Plaintiff's Failure to Warn Claims (Counts I and II).

In Count I, Plaintiff alleges that Defendant breached its duty of reasonable care by "failing to warn [Plaintiff] of the extreme risks associated with F[osamax] and of the possibility of resulting harm which could foreseeably occur." (Doc. 1-1 at 12, ¶ 52.) In Count II, Plaintiff asserts that "Defendant failed to indicate anywhere on related packaging of the risks posed by the use of F[osamax,]" *id.* at 14, ¶ 62, and that she used Fosamax as prescribed and could not have foreseen its risks.

"Under New York law, '[f]ailure to warn claims are identical under strict liability and negligence theories of recovery.'" *DiBartolo v. Abbott Laboratories*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (quoting *Lewis v. Abbott Laboratories*, 2009 WL 2231701, at *5 (S.D.N.Y. July 24, 2009)). "[A] pharmaceutical manufacturer has a duty 'to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of

reasonable care, should have known to exist.'" *Id.* (quoting *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993)).

Because New York follows the learned intermediary doctrine, the drug manufacturer's duty is to warn the physician, not the patient:

> The physician acts as an "informed intermediary" between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient. The warning must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug.

Id. at 611.

"To state a prima facie claim for failure to warn, '[a] plaintiff must demonstrate [1] that the warning was inadequate and [2] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries.'" *Id.* at 611-12 (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990)). "[A] plaintiff must prove both general and specific causation as part of his or her *prima facie* case." *In re Rezulin Prod. Liab. Litig.*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006).

"While the adequacy of warnings is often properly left for jury determination, there are cases . . . where no triable question is raised[.]" *Eiser v. Feldman*, 507 N.Y.S.2d 386, 386 (N.Y. App. Div. 1986) (granting summary judgment for defendant pharmaceutical company on plaintiff's failure to warn claim); *see also Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) (holding that warnings were adequate as a matter of law "[b]ecause the warnings provided specific information on the risks associated with use of the key-free device and [the prescribing doctor] was fully aware of these risks"). "Under [such] circumstances, . . . warnings [may be deemed] adequate as a matter of law." *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 698 (W.D.N.Y. 2017) (finding warning adequate as a matter of law where "[e]ven without additional information regarding specific risk factors, the warnings for [a drug] clearly, directly, and unequivocally informed treating physicians of the increased risk for [a viral brain infection] and the seriousness of that condition").

Under New York law, if a manufacturer has a duty to warn but does not do so or if a required warning exists but is qualitatively inadequate, the manufacturer may be held liable if the failure to warn caused the plaintiff's injury. *See DiBartolo*, 914 F. Supp. 2d at 613 ("[A] court deciding a failure-to-warn claim under New York law must consider not merely the existence of a relevant warning, but also the qualitative adequacy of that warning."). To determine whether a warning is necessary, courts consider that "a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable[.] Knowledge, actual or constructive, of a danger inherent in a product is an essential factor in determining whether a manufacturer is liable[.]" *Mulhall v. Hannafin*, 45 A.D.3d 55, 58 (N.Y. 1st App. 2007) (citations omitted). "In determining whether a warning [i]s [qualitatively] adequate as a matter of law or presents a question of fact for the jury, New York courts 'evaluate the [warning]'s language for its accuracy, clarity and relative consistency.'" *DiBartolo*, 914 F. Supp. 2d at 612 (citation omitted) (third alteration in original).

A warning is accurate "if it is correct, fully descriptive and complete, and . . . conveys updated information as to all of the drug's known side effects." *Id.* (alteration adopted) (omission in original) (internal quotation marks omitted). It is clear "if it employs language that is direct, unequivocal and sufficiently forceful to convey the risk." *Id.* (internal quotation marks omitted). Whether a warning adequately warns of a drug's side effects "depends on the specific manner in which the warning advises physicians of the risk that the side effect will materialize" and whether that manner is "sufficiently accurate, clear, and consistent." *Id.*

Plaintiff began taking Fosamax in 2001 and Defendant did not update its FDA Prescribing Information and Patient Information Sheet to include information about the risk of ONJ in patients taking bisphosphonates until 2005. Plaintiff asserts that the lack of a warning prior to 2005 was tortious. Defendant contends that Plaintiff's failure to proffer any admissible expert testimony that Defendant's Fosamax label was inadequate during any time period that Plaintiff used the medication is fatal to her claim. The court agrees.

An FDA label must "include[] risks that the FDA determines are necessary to

warn patients." *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 84 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 79 (2d Cir. 2021). The "hierarchy of label information" on an FDA-approved label is designed to "'prevent overwarning' so that less important information does not 'overshadow' more important information" and to "exclude 'exaggeration of risk, or inclusion of speculative or hypothetical risks,' that 'could discourage appropriate use of a beneficial drug.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1673 (2019) (alteration adopted). Although "[p]rospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug[,] . . . FDA regulations also acknowledge that information about drug safety may change over time, and that new information may require changes to the drug label." *Id.* (citing 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. §§ 314.80(c), 314.81(b)(2)(i), 314.125(b)(6)).

"Drug manufacturers generally seek advance permission from the FDA to make substantive changes to their drug labels." *Id.* However:

> an FDA regulation called the "changes being effected" or "CBE" regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to "add or strengthen a . . . warning" where there is "newly acquired information" about the "evidence of a causal association" between the drug and a risk of harm.

Id. (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)); *see also Gayle*, 452 F. Supp. 3d at 85 (explaining that the CBE regulation "allows a manufacturer to change its label unilaterally to add or strengthen a contraindication, warning, precaution, or adverse reaction, as soon as there is reasonable evidence of a causal association") (citation and internal quotation marks omitted).

Manufacturers cannot use the CBE process to propose a label change "that is not based on reasonable evidence." *Id.* at 1679 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) ("It is technically a violation of federal law to propose a CBE that is not based on reasonable evidence."). "The FDA has consistently defined reasonable evidence of a causal association as when evidence exists on the basis of which experts qualified by scientific

training and experience can reasonably conclude that the hazard is associated with the use of the drug." *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1272 (W.D. Okla. 2011) (internal quotation marks omitted).

Defendant could not have used the CBE process to update the Fosamax warning label earlier than 2005 without reasonable evidence of a causal association between Fosamax and BRONJ. To prevail on her inadequate warning claim, Plaintiff must therefore show that this reasonable evidence existed prior to 2005 and imposed a duty to warn on Defendant.

Plaintiff argues that at least one court has found that "[s]ince October 2003, there have been published reports of bisphosphonate users developing a rare condition called osteonecrosis of the jaws[.]" *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 170. In that case, as part of multidistrict litigation, the court found that whether a duty to warn of the risk of ONJ arose prior to October 2003 presented issues of material fact to be resolved at trial. *See In re Fosamax Prods. Liab. Litig.*, 647 F. Supp. 2d 265, 275 (S.D.N.Y. 2009) ("Confronted with all of this evidence, a jury could reasonably find that Merck's duty to warn arose before October 2003 and possibly as early as the mid-to-late-1990s."); *In re Fosamax Prods. Liab. Litig.*, 2010 WL 4273310, at *8 (S.D.N.Y. Oct. 22, 2010) ("There are issues of material fact about when Merck had a duty to warn patients of the risk of ONJ[.]"). The court reached that conclusion, however, based on admissible expert opinions that reasonable evidence placed Defendant on notice of the risk of ONJ and imposed a duty a warn of that risk prior to October 2003.

In contrast, in this case, Plaintiff proffers no admissible expert testimony regarding a causal association between Fosamax and ONJ that existed prior to 2005. She cannot reply on other plaintiffs' experts in other cases to fill this gap. Nor is it accurate to claim that no expert witness testimony is required.

"Expert testimony is required in cases involving complex causation issues, including medical device cases, because without it the jury is left to speculate on medical issues with which the average person is unfamiliar." *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 311 (S.D.N.Y. 2016), *aff'd*, 713 F. App'x 11 (2d Cir. 2017).

"Cases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person, and thus expert testimony is required." *Id.* (internal quotation mark and brackets omitted). For this reason, "[t]he FDA, staffed by medical experts, 'frequently takes years to carefully consider the evidence gleaned from multiple studies and reports before approving the form of a final warning.'" *Chandler v. Janssen Pharms., Inc.*, 322 F. Supp. 3d 314, 326 (E.D.N.Y. 2018) (quoting *Montagnon v. Pfizer, Inc.*, 584 F. Supp. 2d 459, 463 (D. Conn. 2008)).

Without expert testimony, a lay jury is not "in [a] position to second-guess the FDA-approved label" that allegedly failed to identify ONJ as a risk. *Id.* (declining to find material issue of fact regarding whether warning label was inadequate where the plaintiff introduced two scientific studies but no expert testimony to interpret the studies). Absent expert testimony, there is no reasonable evidence of a causal relationship between Fosamax and ONJ prior to 2005 giving rise to Defendant's duty to warn, nor is there evidence that Defendant's FDA-approved 2005 warning was inadequate. Accordingly, Plaintiff fails to establish an essential element of her failure to warn claim. "[B]are allegations of inadequacy in [a drug's] warnings are not sufficient to defeat a drug manufacturer's motion for summary judgment." *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1347 (E.D.N.Y. 1992) (quoting *Eiser*, 507 N.Y.S.2d at 388) (first alteration in original).

Even if Defendant's pre- and post-2005 warnings were inadequate, "Plaintiff must also show that Defendant['s] failure to provide a sufficient warning to Plaintiff's prescribing physicians was the proximate cause of [her] injury." *Chandler*, 322 F. Supp. 3d at 327. In a failure to warn action involving "prescription medications, where warnings are directed to prescribing physicians, a plaintiff must demonstrate that had a different, more accurate warning[] been given, [her] physician would not have prescribed the drug in the same manner." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009).

Plaintiff has adduced no evidence that her prescribing treatment provider would have changed or refused to renew her Fosamax prescription if Defendant had provided a

different warning. To the contrary, Plaintiff concedes that CRNP Murphy continued to prescribe Fosamax to Plaintiff after the 2005 ONJ warning was added. By 2007, her dentist, Dr. Lesinski, was aware of the association between oral bisphosphonates and ONJ, but he also did not advise Plaintiff to cease taking them. "This decision by the Plaintiff's physicians to not alter their conduct, despite being apprised of the possible risks associated with [Fosamax], demonstrates that a more stringent warning would have had no practical effect on the physicians' actions." *Id.* Plaintiff therefore cannot establish that the absence of a warning prior to 2005 was the proximate cause of her injuries. *See Gove v. Eli Lilly & Co.*, 394 F. App'x 817, 819 (2d Cir. 2010) (granting summary judgment where, "[b]ecause [plaintiff's] practitioners . . . would not have made different clinical treatment decisions had alternative warnings been provided, [she] . . . failed to establish that [the manufacturer's] allegedly inadequate warnings regarding the potential risks associated with Zyprexa were the proximate cause of her diabetic condition"). "Summary judgment is appropriate where a plaintiff fails to establish that a prescribing physician's decision to prescribe a particular medication would have changed had a different warning been given." *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 408 (S.D.N.Y. 2014).

Because there is no genuine issue of material fact as to the adequacy of Defendant's pre- or post-2005 warnings and whether Plaintiff's treatment providers altered their prescribing decisions if a different warrant was provided, the court GRANTS summary judgment in Defendant's favor on Plaintiff's failure to warn claims (Counts I and II).

E. Whether Defendant Is Entitled to Summary Judgment on Plaintiff's Breach of Implied Warranty of Merchantability Claim (Count IV).

"The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection." *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 433 (2d Cir. 2013) (quoting *Saratoga Spa & Bath, Inc. v. Beeche Sys. Corp.*, 656 N.Y.S.2d 787, 789 (N.Y. App. Div. 1997)). To establish a breach of the implied warranty of merchantability, a

plaintiff must show "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Cowan v. Costco Wholesale Corp.*, 2017 WL 59080, at *5 (E.D.N.Y. Jan. 5, 2017) (internal quotation marks omitted). This inquiry "focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 736 (N.Y. 1995). "The alleged defect may arise from a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product." *Nemes v. Dick's Sporting Goods, Inc.*, 521 F. Supp. 3d 328, 342 (S.D.N.Y. 2021) (internal quotation marks omitted).

"[T]he New York Court of Appeals has taken care to distinguish this merchantability-related strict liability from the liability that is more typically associated with claims for defective products." *Caronia*, 715 F.3d at 434. While "[a]s a practical matter, the distinction between the defect concepts in tort law and in implied warranty theory may have little or no effect in most cases[,]" in this case the distinction is dispositive. *Denny*, 662 N.E.2d at 738. For an implied warranty of merchantability claim, "recovery may be had upon a showing that the product was not minimally safe for its expected purpose—without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition." *Id.* at 736; *see also Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 422 (S.D.N.Y. 2011) ("Plaintiff's ability to recover under his breach of implied warranty claim is not affected by the feasibility of making the product safer[.]").

Plaintiff has produced no evidence that, at any time, Fosamax was not "minimally safe" as required by New York law. *Caronia*, 715 F.3d at 434 ("That implied warranty is not breached if the cigarettes were minimally safe when used in the customary, usual, and reasonably foreseeable manner."). "This standard does not require that the goods be perfect, or that they fulfill [a] buyer's every expectation; it requires only that the goods sold be of a minimal level of quality[.]" *Id.* at 433-34 (internal quotation marks and citations omitted). Even Plaintiff's expert witness, Dr. Morhaim, concedes that Plaintiff's

risk of developing ONJ was "very low" and Fosamax's benefits exceed the risks of developing ONJ.

Because "[i]n opposing the instant motion for summary judgment, Plaintiff has failed to adduce sufficient evidence . . . that Fosamax is not minimally safe," *In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 489 (S.D.N.Y. 2013), summary judgment in Defendant's favor must be granted. *See Catrett*, 477 U.S. at 322 (holding summary judgment is mandated against a party "who fails to make a showing sufficient to establish the existence of an element essential to that party's case"); *El-Nahal v. Yassky*, 835 F.3d 248, 252 (2d Cir. 2016) (holding that "a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial") (internal quotation marks omitted).

For the reasons stated above, the court hereby GRANTS Defendant's motion for summary judgment on Plaintiff's breach of implied warranty of merchantability claim (Count IV).

CONCLUSION

For the foregoing reasons, the court GRANTS IN PART and DENIES IN PART Defendant's motion to exclude the testimony of Dr. Sam Morhaim and Dr. Shehzad Merchant (Doc. 26) and GRANTS Defendant's motion for summary judgment (Doc. 27).

SO ORDERED.

Dated this 14th day of June, 2023.

Christina Reiss, District Judge
United States District Court